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SECTION 5, 510(k) Summary K121525

AUG 2 2012

Company Information:

Smiths Medical ASD, Inc.
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Keene, NH 03431
(781)763-9404
Contact: Christine Lloyd
Regulatory Affairs Specialist
Summary Prepared: June 28, 2012

Product Name:

Trade Name: PeriFuse™ Catheter
Common Name: Anesthesia Conduction Kit
Classification Name: Anesthesia Conduction Kit, (21 CFR 868.5140, Product Code CAZ)

Predicate Device(s):

Primary Predicate	K001129, ProLong® Regional Anesthesia Catheter, Model PL50, PL100, PL150
Secondary Predicate	K994275, SIMS Portex Anesthesia Catheter

Reference Device(s):

K033084, Wallace (SureView™) Embryo Replacement Catheters & Trial Transfer Catheters

Device Description

The PeriFuse™ Catheter is an echogenic regional anesthesia catheter intended to enhance visibility of the catheter under ultrasound guidance. The PeriFuse™ Catheter is made of flexible nylon tubing and comes in two versions. One version is a closed end with 3 lateral eyes. The second version is an open end with a finished tip. The catheters are available as 21G (O.D. 0.83mm nominal/I.D. 0.41mm nominal) and have a nominal length of 944mm. They will be provided as sterile, single use, disposable devices.

The PeriFuse™ Catheter tip is marked for ease of identification and to ensure complete catheter removal. The catheter is extruded using a patented Smiths Medical technology which leaves a surface finish that is slightly textured on both the inner diameter and outer diameter

The PeriFuse™ Catheter may be packaged in either a catheter kit or may be included in Smiths Medical regional anesthesia trays (K965017).

Indications for Use:

The PeriFuse™ regional anesthesia Catheter is indicated for use during procedures where intermittent administration of local anesthetics is indicated for control of operative, post-operative, acute or chronic pain for peripheral nerve block procedures. The duration of use should not exceed 72 hours.

Technological Characteristics:

- The proposed device and the predicate devices are nylon catheters for regional anesthesia use for peripheral nerve blocks.
- Both the proposed and predicate devices are 21G catheters.
- Both the proposed and predicate catheters are closed end 3 eye design.
- Both the proposed and secondary predicates are open ended, no eye design.
- The proposed PeriFuse™ Catheters are available in a styleted version the same as the secondary predicate catheters.
- The proposed PeriFuse™ Catheter incorporates a bubbling technology to enable the catheter to be visible under ultrasound guidance. The reference devices, the Wallace (SureView™) Embryo Replacement Catheters & Trial Transfer Catheters, are provided to show the acceptable use of this technology in medical devices. This patented technology is used in the cleared Wallace (SureView™) Embryo Replacement Catheters to enable the physician to guide the catheter into the proper position in the uterus to properly place the viable embryo into position during reproductive procedures.

All statements and representations set forth herein regarding or related to "substantially equivalent" or "substantial equivalence" are in the limited context of the definition and purpose of substantial equivalence in the Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations of the Food and Drug Administration (FDA), and are not made in the context of, for any purpose related to, or as an admission against interest under, any other laws or regulations, including patent laws (whether in the context of patent infringement or otherwise).

Non-Clinical Data:

Non-clinical testing for the PeriFuse™ Catheter has been conducted including mechanical, functional and performance. The PeriFuse™ Catheter meets the requirements of the stated sections of *BS 6196:1989 Sterile epidural catheters and introducer needles for single use.*

Clinical Data:

Not required.

Conclusion:

The comparison to the predicate catheter devices demonstrates that the proposed PeriFuse™ Catheter is safe and effective and is substantially equivalent to the predicate catheter devices.

Sincerely,

SMITHS MEDICAL ASD, INC.
Christine Lloyd
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Christine Lloyd
Regulatory Affairs Specialist
Smiths Medical ASD, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431

AUG 2 2012

Re: K121525
Trade/Device Name: PeriFuse™ Catheter
Regulation Number: 21 CFR 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: May 22, 2012
Received: May 23, 2012

Dear Ms. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): K121525

Device Name: **PeriFuse™ Catheter**

Indications for Use:

The PeriFuse™ regional anesthesia Catheter is indicated for use during procedures where intermittent administration of local anesthetics is indicated for control of operative, post-operative, acute or chronic pain for peripheral nerve block procedures. The duration of use should not exceed 72 hours.

Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121525